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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,539	01/11/2002	Ambrose L. Cheung	11312-006-999 (DC-0199)	.7285

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/043,539	<b>Applicant(s)</b> CHEUNG ET AL.	
	<b>Examiner</b> Ginny Portner	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28 is/are allowed.
- 6) ☒ Claim(s) 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 28 and 30 are pending; claims 29 and 31 have been canceled.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Allowable Subject Matter*

2. Claim 28 defines over the prior art of record and is allowed.

#### *Withdrawn Rejections*

3. **Rejections Withdrawn Double Patenting:** The rejection of claim 30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 5,587,288 in light of the amendment of claim 30 to recite SarR protein, which excludes the allowed SarA composition.
4. **Objection Withdrawn Specification** The disclosure objected to because it contains an embedded hyperlink and/or other form of browser-executable code has been obviated by Applicant by amendment of page 30, to remove the phrase [www.tiger.org](http://www.tiger.org).
5. **Rejection Withdrawn:** Claims 28 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the *written description* requirement in light of the amendment of claim 28 to recite SEQ ID NO 2.
6. **New Objection to the Specification withdrawn:** The disclosure is objected to because of the following informalities: The Amendment of page 24, starting at line 28 does not correspond to the disclosure of the Specification submitted as originally filed. The Objection to the Specification for a hyperlink was made with respect to disclosure set forth on page 30 of the instant Specification. The amendment of page 24 should be page 30. In light of the amendment of page 30, the objection is herein withdrawn.
1. **Rejection Withdrawn, Claim Rejections - 35 USC § 112** Claims 28 and 30 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Original descriptive support for SarR protein that comprise the polynucleotide sequence of SEQ ID NO 1 could not be found in the instant Specification. Therefore, claims 28 and 30 recite a combination of claim limitations that were NEW MATTER, but is here in withdrawn in light of the amendment of claim 28 to recite SEQ ID NO 2.
2. The phrase "identified by" has been canceled and the rejection of Claim 30 is herein withdrawn with respect to insufficient antecedent basis for this limitation in the claim. Claim 28 does not claim a methods step of identifying the compound in the heterodimer complex.

***Response to Arguments***

7. Applicant's arguments filed July 18, 2006 have been fully considered but they are not persuasive.

8. ***Rejection Maintained, Claim Rejections - 35 USC § 112(written description)*** *The rejection of claim 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is asserted that claim 28 has been amended to recite SEQ ID No 2 and "one of skill in the could readily carry out the instant assay and identify lead compounds that inhibit the expression of Sara in Staphylococcus."*

9. It is the position of the examiner that the method of claim 28 has been indicated as allowable, but the compounds of claim 30 which are analogs of any Staphylococcal accessory regulatory protein still lack written description for reasons of record.

10. While claim 30 has been amended to recite "a SarR protein from *S. aureus*, *S.epidermidis*, *S.haemolyticus* and *S.Saprophyticus* which inhibits the expression of *sarA*", the SarR is an analog of the disclosed proteins, in light of the combination of limitations setforth in claim 28 which requires analogs to be screened. A genus of analog SarR proteins from the recited sources that have the claimed functionality of a pharmaceutical composition have not been so described in such a way as to reasonably convey to one of skill in the relevant art that the inventors, at the time the application was filed had possession of the claimed invention. The lack of written description over claim 30 is maintained for reasons of record.

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10. **Rejection Maintained** Claim 30 rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to SarR protein from *Staphylococcus aureus*, *epidermidis*, *haemolyticus* and *saprophyticus*. See M.P.E.P. §§ 706.03(n) and 706.03(z), is traversed on the grounds that Applicant's have provided the crystal structure of SarR and SarR analogs from *S. epidermidis*, *S. haemolyticus* and *S. saprophyticus* and one of skill in the art could envision and produce Sar R mutants without undue experimentation in view of the teachings of Topham et al.

3. It is the position of the examiner that the claim 30 is not limited to any specific analogs of SarR protein from *S. epidermidis*, *S. haemolytic* or *S. saprophyticus*, nor is it limited to mutations at any specific locations within a reference sequence (SEQ ID NO 2). The instant Specification proposes to identify small molecules and other analogs from chemical libraries that would serve to bind to and inhibit expression of sarA in *Staphylococcus*. A proposed method of identifying, possible locations for making changes does not describe a molecule that will form a heterodimer with SarA which in turn will function as a pharmaceutical composition. While a person of skill in the art may be able to make analogs of SarA of SEQ Id NO 2, the instantly claimed highly variable genus of analogs that would serve as a pharmaceutical composition has not been described (see written description rejection of record), and what has not been described has not been enabled, despite the fact that a person of skill in the art could make analogs, the ability of the analog to treat or prevent *Staphylococcal* infection and disease is unpredictable in the art of vaccines, and thus the function of the analog as a pharmaceutical composition is not evident until the analog is actually tested and evaluated in vivo or an art recognized in vitro method. The instant Specification does not show or nor provide guidance on how *any SarR analog* could or

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would function as a pharmaceutical composition when the changes from the reference SarR protein sequence may be any number of changes. The scope of enablement is maintained for reasons of record, and responses set forth above.

4. ***Rejections Maintained Claim Rejections - 35 USC § 102*** Claim 30 rejected under 35 U.S.C. 102(a) as being anticipated by Tegmark et al (2000) ;Claim 30 rejected under 35 U.S.C. 102(b) as being anticipated by Manna et al (1998) in light of evidence provided by Manna et al (2001); Claim 30 rejected under 35 U.S.C. 102(e) as being anticipated by Hurlburt et al (US Pat. 6,699,662 B1); **102** Claim 30 is rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al (US Pat. 6380370, SEQ ID No 4993, filing date August 13, 1998)

Are collectively traversed is traversed on the grounds that “these references do not teach or suggest the claimed SarR protein which inhibits the expression of sarA. Because these references fail to teach each and every element of that which is claimed, these references cannot be held to anticipate the present invention.”

1. It is the position of the examiner that claim 30 is still anticipated by the SarR analog of **Tegmark et al** that would function as an isolated and purified compound composition,; no evidence has been made of record to show that the compound would not function in the recited manner. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true

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when it is not a property but an ingredient which is inherently contained in the prior art.

5. It is the position of the examiner that claim 30 is still pending and no evidence has been made of record to show the SarR analog of Manna et al would not function as an isolated and purified compound composition. The rejection of claim 30 is maintained for reasons of record.

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

6. **Rejection Maintained:** Claim 30 rejected under 35 U.S.C. 102(e) as being anticipated by Hurlburt et al (US Pat. 6,699,662 B1) is traversed on the grounds that "the reference does not teach or suggest a SarR analog of a SarR protein having an amino acid sequence comprising SEQ ID NO 1 or heterodimer formation of the SarR analog with SarA to inhibit expression of sarA of staphylococcus.

7. It is the position of the examiner that no evidence was made of record to show the isolated and purified compound of Hurlburt et al would not function as a pharmaceutical composition. The rejection of claim 30 is maintained for reasons of record.

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8. ***Rejection Maintained, Claim Rejections - 35 USC § 102*** Claim 30 rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al (US Pat. 6380370, SEQ ID No 4993, filing date August 13, 1998) is traversed on the grounds that the SarR compound is not shown to form a heterodimer with SarA.

9. It is the position of the examiner that what is claimed is not a heterodimer, but an isolated and purified analog of an SarR protein of SEQ ID NO 2. The structure of Doucette-Stamm et al is an analog of SEQ ID NO 2, or an analog encoded by SEQ ID 1, the Staphylococcal polypeptide compound of Doucette-Stamm et al shares 84.2% sequence identity with SEQ ID NO 2, and is therefore an analog of SarR obtained from Staphylococcus with the recited intended use as a therapeutic (see title). The composition anticipates the instantly claimed invention as now claimed. Sequence alignment provided herewith. The functional characteristics are defined by the chemical structure of the protein SarR analogs, and would therefore inherently evidence the same or equivalent function recited in the claims. *Atlas Powder Co. v IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art."

10. ***Provisional Double Patenting Maintained*** Claim 28 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22



of copending Application No. 11/063308. This rejection was not addressed and therefore maintained for reasons of record.

***Amended New Claim Limitations/New Grounds of Rejection/Objection***

***Claim Rejections - 35 USC § 112***

11. Claim 30 recites the limitation "Staphylococcus aureus, S. epidermidis, S. haemolyticus or S.saprophyticus" in dependent form from claim 28 which recites "one or more Staphylococcal" of which there are at least 12 known species. Claim 28 is directed to analogs of SarR proteins, the proteins claimed in claim 30 are analogs of specific species of SarR proteins which are not specifically recited in claim 28. There is insufficient antecedent basis for this limitation in the claim.

12. Additionally, the new combination of claim limitations define that the pharmaceutical composition is directed to "isolated and purified lead compound of claim 28"; this phrase lacks antecedent basis in claim 28 from which claim 30 depends. The method of claim 28 is directed to a method of "screening", and does not confirm that the compounds are "lead compounds" but determines the presence of a heterodimer that is "indicative of a lead compound". None of the heterodimers are dissociated, nor does the method of claim 28 recite additional methods steps which result in the formulation of a pharmaceutical composition. The deletion of claim limitations to resolve a lack of antecedent basis, and the amendment of claim 30 still results in a lack of antecedent basis for the new combination of claim limitations set forth in claim 30.

***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, A. Mark Navarro can be reached on (571) 272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp  
September 28, 2006



MARK NAVARRO  
PRIMARY EXAMINER